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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference PH/8626PCT1 | FOR FURTHER ACTION | | See Form PCT/IPEA/416 |
| International application No. PCT/GB2005/000051 | International filing date (day/month/year) 10.01.2005 | Priority date (day/month/year) 08.01.2004 | |
| International Patent Classification (IPC) or national classification and IPC A61B5/00, A61B5/103 | | | |
| Applicant DIALOG DEVICES LIMITED et Al. | | | |

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| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 4 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of 7 sheets, as follows:</p> <ul style="list-style-type: none"> <input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |
| <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application |

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| Date of submission of the demand 08.08.2005 | Date of completion of this report 23.02.2006 |
| Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | <p>Authorized Officer Manschot, J Telephone No. +49 89 2399-6588</p>  |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/GB2005/000051

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3 and 23.1(b))
 - publication of the international application (under Rule 12.4)
 - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

| | |
|-------------|--|
| 2, 7-18 | as originally filed |
| 1, 1a, 3, 6 | received on 08.08.2005 with letter of 08.08.2005 |

Claims, Numbers

| | |
|------|--|
| 1-16 | received on 08.08.2005 with letter of 08.08.2005 |
|------|--|

Drawings, Sheets

| | |
|----------|---------------------|
| 1/2, 2/2 | as originally filed |
|----------|---------------------|

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:
 - the description, pages
 - the claims, Nos.
 - the drawings, sheets/figs
 - the sequence listing (*specify*):
 - any table(s) related to sequence listing (*specify*):

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

the description, pages
 the claims, Nos.
 the drawings, sheets/figs
 the sequence listing (*specify*):
 any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2005/000051

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-16 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | 1-16 |
| | No: Claims | |
| Industrial applicability (IA) | Yes: Claims | 1-16 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

Section V

1. Reference is made to the following documents:
D1: US-A-5 137 023 (MENDELSON ET AL) 11 August 1992
D2: WO 98/17174 A (CARDIAC CRC NOMINEES PTY. LIMITED; COOPER, PHILIP, GEORGE) 30 April 1998
D3: DE 37 44 538 A1 (A. NATTERMANN & CIE GMBH) 13 July 1989
2. The subject-matter of the present set of claims meets the criteria of Article 33(1) PCT, for the following reasons:

Document D1 discloses (see column 7, line 28 to column 8, line 15):
a system (and implicitly a method of using the system) comprising measurement means (5) for measuring a parameter (light transmission) dependent on the blood volume in a limb (e.g. forearm or fingertip: column 8, lines 38-39); means (15,17) for separating the parameter in a first pulsating component (AC) and a second non-pulsating (DC) component; and processing means for calculating an indicator (AC/DC) which is the ratio of the first and the second component. The posture is unchanged for the first and second component and may be considered "a first posture."

3. The subject-matter of independent claims 1 and 11 relates to assessing the blood circulation in a subject's limb by calculating an indicator based upon (the ratio) of a signal for the (arterial) blood volume in the limb of a first and second (different) posture.
This is not known or hinted at in the prior art. In D2 (page 8, line 23 to page 10, line 15), e.g., the difference between the signals (at each wavelength) detected with postural changes is calculated, whereafter the ratio of the differences is calculated in order to obtain an indication for the blood oxygen level. No ratio of signals following postural changes is indicated.
Document D3 uses a postural change in order to empty the veins, without comparing blood volumes before and after the change.

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TITLE

A system or method for assessing a subject's peripheral blood circulation

5 FIELD OF THE INVENTION

Embodiments of the invention relate to assessing a subject's peripheral blood circulation, in particular, but not exclusively, arterial blood flow to the foot.

10 BACKGROUND TO THE INVENTION

US 5137023 discloses a non-invasive system for measuring the concentration of an analyte such as glucose, in an absorbing matrix. WO 98/17174 describes a non-invasive method for determining the absolute level of oxygen saturation in blood. Both of these documents describe the taking of measurements at different wave lengths of light.

Healthy peripheral circulation is an important factor in quality of life, independent living and personal freedom. Disorders of the vascular system can arise from a number of diseases such as, for example, diabetes, arteriosclerosis, Reynard's syndrome, atherosclerosis.

There are a few clinic/GP based technologies that are used currently to assess peripheral blood circulation. However, these technologies are generally interpretive and must be practised by a correctly trained person.

BRIEF DESCRIPTION OF THE INVENTION

It would be desirable to provide for the objective assessment of peripheral blood circulation.

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According to one aspect of the invention, there is provided a system for assessing blood circulation in a subject's limb, comprising: detection means 5 for detecting a signal dependent upon the arterial blood volume in a limb of the subject when the subject is in a first posture and also when the subject is in a second posture, different to the first posture; and processing means for

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first exponent). A good approximation of the first exponent may be obtained, for example, by taking the ratio of the ac component of the measured parameter to the dc component of the measured parameter. Also according to this model, the first exponent comprises a factor that represents the light 5 absorbency of the subject's arterial blood and a factor that represents the volume of the subject's arterial blood. According to this model, as the light absorbency of a subject's arterial blood remains constant between postural changes, then the ratio of the first exponent for a first posture to the first exponent for a second posture gives a 'pure' ratio of arterial volumes without 10 other factors. This ratio can therefore be used as an objective quantitative indicator.

Embodiments of the invention therefore provide a quantitative indicator in a robust and quick manner at modest cost without discomfort to the user. Some 5 embodiments may be automated,

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention reference will now be made by way of example only to the accompanying drawings in which:

10 Fig. 1 schematically illustrates a system 10 for the objective assessment of blood perfusion in a lower limb 12 of a subject;

Fig. 2 illustrates a system 10 for the objective assessment of blood perfusion in a lower limb 12 of a subject using an optical sensor 4;

Fig. 3 schematically illustrates the components of the system illustrated in Fig. 2.

15 Figs. 4A and 4B illustrate the change in pulsatile perfusion for a healthy subject's leg when raised to 30 degrees; and

Figs. 5A and 5B illustrate the change in pulsatile perfusion for an at risk subject's leg when raised to 30 degrees.

20 DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

CLAIMS

1. A system (10) for assessing blood circulation in a subject's limb (12), comprising:
 - 5 detection means (4, 60) for detecting a signal (I_{Ac}) dependent upon the arterial blood volume in a limb (12) of the subject when the subject is in a first posture and also when the subject is in a second posture, different to the first posture; and processing means (56) for calculating a quantitative indicator (R, R') that is dependent upon the ratio of the signal for the first posture ($I(1)_{Ac}$) to the signal for the second posture ($I(2)_{Ac}$).
 - 10
 - 15
 2. A system (10) as claimed in claim 1, wherein the quantitative indicator (R, R') is directly proportional to the ratio of the signal for the first posture ($I(1)_{Ac}$) to the signal for the second posture ($I(2)_{Ac}$).
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 3. A system (10) as claimed in claim 1 or 2, wherein the signal is a pulsating component (I_{Ac}) of a measured parameter (I), the measured parameter being dependent upon the blood volume in the subject's limb.
 4. A system (10) as claimed in claim 3, wherein the calculation of the quantitative indicator (R, R') is additionally dependent upon the ratio of a non-pulsating component of the measured parameter for the second posture ($I(2)_{DC}$) to a non-pulsating component of the measured parameter for the first posture ($I(1)_{DC}$).
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 5. A system (10) as claimed in claim 4, wherein the quantitative indicator is directly proportional to the ratio of the non-pulsating component of the measured parameter for the second posture ($I(2)_{DC}$) to the non-pulsating component of the measured parameter for the first posture ($I(2)_{DC}$).

6. A system (10) as claimed in any preceding claim, wherein the detection means (4, 60) comprises measurement means (4) operable to measure a parameter (I) indicative of the blood volume of the subject's limb when the subject is in a first posture and to measure the parameter when the subject is in a second posture and comprising means for isolating (51) a pulsating component (I_{AC}) of the measured parameter.
7. A system (10) as claimed in any preceding claim wherein the limb (12) is a foot.
8. A system as claimed in any preceding claim, wherein the position of the limb (12) is changed between the first posture and the second posture.
9. A system (10) as claimed in any preceding claim, wherein, in the first posture the limb (12) is at a first elevation and in the second posture the limb (12) is at a second elevation.
10. A system (10) as claimed in any one of claims 3 to 9, wherein the measured parameter (I) is the intensity of light reflected from the limb (12) and the ratio of the signal for the first posture to the signal for the second posture reduces subject dependent influences such as variable light absorption of the blood and tissue in the limb for different subjects.
11. A method for assessing blood circulation in a subject's limb (12), comprising:
detecting a signal (I(1)_{AC}) dependent upon the arterial blood volume in a limb (12) of the subject when the subject is in a first posture;

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detecting the signal ($I(2)_{Ac}$) dependent upon the arterial blood volume in the limb of the subject when the subject is in a second posture, different to the first posture; and

5 calculating a quantitative indicator (R, R') that is dependent upon the ratio of the signal for the first posture ($I(1)_{Ac}$) to the signal for the second posture ($I(2)_{Ac}$).

12. A method as claimed in claim 11, further comprising:

10 measuring a parameter (I) that is dependent upon the blood volume in the subject's limb (12); and

isolating, as the signal (I_{Ac}), a pulsating component of the measured parameter (I).

13. A method as claimed in claim 12, further comprising:

15 isolating a non-pulsating component (I_{DC}) of the measured parameter (I), wherein the quantitative indicator is additionally dependent upon the ratio of the non-pulsating component of the measured parameter for the second posture ($(I(2)_{DC})$ to the non-pulsating component of the measured parameter for the first posture ($(I(1)_{DC})$).

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14. A method as claimed in claim 13, wherein the limb (12) is a foot.

15. A method as claimed in any one of claims 11 to 14, wherein the position of the limb (12) is changed between the first posture and the second posture.

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16. A method as claimed in any one of claims 11 to 15 wherein, in the first posture the limb (12) is at a first elevation and in the second posture the limb (12) is at a second elevation.